



Food and Drug Administration
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December 23, 2014

Nvision Biomedical Technologies, LLC
% Ms. Jennifer Palinchik
JALEX Medical, LLC
27881 Clemens Road, Suite 2
Westlake, Ohio 44145

Re: K142328
Trade/Device Name: nv^c
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: November 25, 2014
Received: November 26, 2014

Dear Ms. Palinchik:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Lori A. Wiggins -S

for

Mark N. Melkerson

Director,

Division of Orthopedic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K142328

Device Name

nv^c

Indications for Use (Describe)

The nv^c is intended for spinal fusion procedures at one level, from C2-T1, in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine. DDD is defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies. One device is to be used per intervertebral space. Patients should receive six weeks of non-operative treatment prior to treatment with an intervertebral body fusion device. The nv^c devices must be used with supplemental fixation and are designed for use with autograft bone to facilitate fusion. The devices are to be implanted via an anterior approach.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”

510(k) Summary

Submitted By: Nvision Biomedical Technologies, LLC
18618 Tuscany Stone, Suite 120
San Antonio, TX 78258

Date: October 29, 2014

Contact Person: Jennifer Palinchik
Regulatory Consultant

Contact Telephone: (440) 930-2015

Device Trade Name: nv^c
Classification Name: Intervertebral Body Fusion Device
Device Classification: Class II
Reviewing Panel: Orthopedic
Regulation Number: 888.3080
Product Code: ODP
Predicate Device: Primary Predicate: X-Spine Calix™ Cervical Interbody Spacer (K083637)
Other Predicate: Genesys Spine Apache™ Cervical Interbody System (K103034)
These predicates have not been subject to a design-related recall.

Device Description:

The nv^c is an intervertebral body fusion device used in the cervical spine following discectomy. All devices are manufactured from PEEK Optima® LT1 per ASTM F2026 and include tantalum markers per ASTM F560 for radiographic visualization.

The devices have multiple footprints to adapt to the general shape of the vertebral endplates and have a hollow centre to accommodate bone graft. The devices are implanted via an anterior (ACIF) surgical approach. Each footprint is available in multiple heights to accommodate patient variability and there are anti-migration features on the superior and inferior surfaces designed to improve fixation, stability and prevent back out.

Intended Use:

The nv^c is intended for spinal fusion procedures at one level, from C2-T1, in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine. DDD is defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies. One device is to be used per intervertebral space. Patients should receive six weeks of non-operative treatment prior to treatment with an intervertebral body fusion device. The nv^c

devices must be used with supplemental fixation and are designed for use with autograft bone to facilitate fusion. The devices are to be implanted via an anterior approach.

Comparison of Technological Characteristics:

The technological characteristics of the nv^c device, including materials, size, shape and usage were compared to a predicate device. The comparison of information provided in this Premarket Notification supports the substantial equivalence, material information, and analysis of data.

Mechanical Testing:

Performance testing was conducted in accordance with the following standardized tests:

- Static and Dynamic Axial Compression per ASTM F2077
- Static and Dynamic Torsion per ASTM F2077
- Subsidence per ASTM F2267
- Expulsion

The results of the performance testing demonstrate substantial equivalence of the nv^c to the predicate device.

Conclusion:

Non-clinical data presented in this Premarket Submission supports the substantial equivalence of the subject device to the predicate. Based on the indications for use, technological characteristics, and comparison with the predicate device, the subject device has demonstrated substantial equivalence.